IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DEY, L.P. and DEY, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 08-372 (JJF)
	)	
SEPRACOR INC.,	)	
	)	
Defendant.	)	
	)	
	)	

DEY, L.P.'S AND DEY, INC.'S BRIEF IN OPPOSITION TO SEPRACOR'S MOTION TO DISMISS

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I. INTRODUCTION

Sepracor's motion to dismiss must be denied because as recently as five months ago the Federal Circuit in *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, rejected the same arguments that Sepracor asserts in this motion. 527 F.3d 1278 (Fed. Cir. 2008). In *Caraco*, the Federal Circuit reversed a district court's dismissal of a declaratory judgment action brought by a subsequent Abbreviated New Drug Application ("ANDA") applicant against the New Drug Application ("NDA") patent holder who had given the ANDA holder a covenant not to sue. Applying the Supreme Court's "all-the-circumstances test" to a factual situation almost identical to the one currently before this Court, the Federal Circuit held a justiciable declaratory judgment controversy existed.

According to the Federal Circuit, an action is justiciable under Article III where: (1) the plaintiff has standing; (2) the issues presented are ripe for judicial review; and (3) the case has not been rendered moot at any stage in the litigation. As detailed below, all three prongs of the test are met in this case. In arguing that Dey's action is not justiciable because "Dey apparently has never believed itself under any threat of suit" on the '289 patent, Sepracor applies the "reasonable apprehension of suit" test. (Sepracor Br. at 1). But the Supreme Court abrogated this test in *MedImmune, Inc. v. Genentech, Inc.* and held the "all-the-circumstances test" is the appropriate test for determining whether an Article III controversy exists. *See* 127 S. Ct. 764, 771 (2007). Indeed, when Sepracor discusses the "all-the-circumstances test" at the end of its brief it does not even attempt to apply the factors identified by the Federal Circuit. (Sepracor Br. at 14-15). To do so would not lead to Sepracor's desired result.

Sepracor argues that *Caraco* was decided on very narrow facts and tries unsuccessfully to distinguish *Caraco* from this case. There is no material distinction. In *Caraco*, as in this case, the second ANDA filer was involved in litigation on one or more Orange Book patents at the

time it filed its declaratory judgment action to resolve the Orange Book patent it was not sued on. It is unclear why Sepracor argues that the ongoing litigation on the five Orange Book patents in this case renders the injury of delayed market entry hypothetical, whereas in *Caraco* the ongoing litigation on the Orange Book patent rendered the injury of delayed market entry immediate. The material facts of *Caraco* cannot be distinguished from the material facts of this case.

Sepracor's motion to dismiss asks this Court to ignore controlling precedent. Sepracor's motion should be seen for what it is—a transparent attempt to add to the series of delays Sepracor has contrived to slow down resolution of its Hatch-Waxman levalbuterol cases against Dey, and thereby delay the public's access to lower-cost generic levalbuterol. As the Federal Circuit noted in *Caraco*, "NDA holders have a strong incentive to avoid litigation that would trigger the first Paragraph IV ANDA filer's exclusivity period and allow the FDA to approve subsequent Paragraph IV ANDAs 181 days after the triggering event." *Caraco*, 527 F.3d at 1284. This Court should reject Sepracor's motion to dismiss and conclude that Dey's declaratory judgment complaint presents a justicable controversy over which this Court has subject matter jurisdiction.

II. STAUTORY BACKGROUND AND STATEMENT OF FACTS

A. The Hatch-Waxman Statutory Scheme

This case arises under the Drug Price Competition and Patent Term Restoration Act of 1984 ("the Hatch-Waxman Act"), which governs the approval of new and generic drugs. 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e) . The goal of the Hatch-Waxman Act is to strike "a balance between two competing policy interests: (1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002). The Hatch-Waxman Act achieves this goal, in part, by reducing delays in Food and Drug

Administration ("FDA") approval of generic versions of approved drugs by allowing generic drug manufacturers to submit to the FDA an ANDA, instead of an NDA. *See* 21 U.S.C. § 355(j); H.R. Rep. No. 98-857, pt. 2 at 8-10 (1984).

1. The Abbreviated New Drug Application Process

The ANDA process allows the FDA to approve a bioequivalent drug by relying on the safety and efficacy studies previously submitted in a NDA. Under the Hatch-Waxman Act, a NDA filer is required to inform the FDA of all patents covering the drug or methods of using that drug, which may be asserted in an action for patent infringement. *See* 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists all patents submitted by the NDA holder in a publication entitled the "Approved Drug Products With Therapeutic Equivalence Evaluations" ("the Orange Book"). An ANDA applicant must file one of four certifications addressing each patent listed in the Orange Book ("Orange Book patents"). 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). The fourth certification, commonly referred to as a "Paragraph IV Certification," is a statement by the ANDA applicant that the identified patent is invalid and/or not infringed by the proposed generic drug.

When, as in the present case, a generic applicant files an ANDA with a Paragraph IV Certification, the filing of the ANDA is deemed to be a technical act of infringement under the Hatch-Waxman Act. *See* 35 U.S.C. § 271(e)(2). As the Federal Circuit explained, "§ 271(e)(2) is designed to create an *artificial* act of infringement for purposes of establishing jurisdiction in the federal courts." *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004). Once a patentee receives a Notice of Paragraph IV Certification, the patentee may sue the ANDA applicant for infringement of one or more of the Orange Book patents. If the patentee does not sue within 45 days, the FDA may approve the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). If the patentee sues, as in this case, the FDA may not approve the ANDA for 30 months or until the

entry of a final judgment that each of the Orange Book patents-in-suit is not infringed or is invalid, whichever comes first. *Id.*

2. The Medicare Modernization Act of 2003 and Its Forfeiture Provision

To incentivize generic drug manufacturers for undertaking the risk of being sued, the Hatch-Waxman Act provides 180 days of market exclusivity for the generic applicant that is the first to file an ANDA with a Paragraph IV Certification ("first filer"). 21 U.S.C. § 355(j)(5)(B)(iv). Until this 180-day exclusivity period expires, the FDA may not give final approval to a subsequently-filed ANDA with a Paragraph IV Certification. 21 U.S.C. § 355(j)(5)(B)(iv). Prior to the amendment of the Hatch-Waxman Act in 2003, it was not uncommon for first filers and NDA holders to settle litigations under conditions that delayed the first filer's market entry. These settlements allowed the first filer to maintain or "park" its exclusivity, thereby, preventing subsequent ANDA holders from obtaining final approval. These agreements frustrated the policy objectives of Congress—namely, to get low-cost generic equivalents on the market.

In December 2003 Congress passed Title XI of the Medicare Modernization Act of 2003 ("MMA") entitled "Access to Affordable Pharmaceuticals," in part, to curb abuses that NDA holders had developed over the years to delay the market entry of ANDAs. The MMA included forfeiture provisions to eliminate the delays in FDA granting final approval because the first filer entered into a settlement agreement which "parked" the 180-day market exclusivity of the first filer and prevented subsequent filers from entering the market. Specifically, the MMA provides that the 180-day exclusivity period "shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant." 21 U.S.C. § 355(j)(5)(D)(ii). Under the MMA, a subsequent ANDA filer can trigger the first filer's exclusivity if a judgment or consent decree of invalidity or non-infringement is entered as to each Orange Book patent the first filer certified

under Paragraph IV ("the court-judgment trigger"). 21 U.S.C. § 355(j)(5)(B)(iv)(II). Additionally, the 180-day period of exclusivity may begin on the date that the first filer begins marketing its ANDA product ("the commercial-marketing trigger"). 21 U.S.C. § 355(j)(5)(B)(iv)(I).

Because the FDA cannot approve a subsequent Paragraph IV ANDA until the first filer's 180-day exclusivity period expires, the potential for a "bottleneck" situation exists. For example, if the first filer is liable for infringement, then it cannot trigger its exclusivity period through the court-judgment trigger or the commercial-marketing trigger. Under these circumstances, subsequent Paragraph IV ANDA filers must obtain a court-judgment triggering event in order to activate the first filer's 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv)(II). The subsequent ANDA filer can do this only by obtaining entry of a final judgment, settlement or consent decree (collectively "consent decree") that all of the Orange Book patents the first filer certified to under Paragraph IV are invalid or not infringed. If the NDA holder can prevent the subsequent Paragraph IV ANDA filer's court challenge, it can effectively delay the approval of the subsequent Paragraph IV ANDA and thus the subsequent filer's entry into the market. 21 U.S.C. § 355(a). As the Federal Circuit recently noted, "NDA holders have a strong incentive to prevent a triggering event, because subsequent Paragraph IV ANDAs cannot be approved until the exclusivity period expires." *Caraco*, 527 F.3d at 1284.

Patentees can block a subsequent ANDA applicant's entry into the market in other ways: (1) by suing on only some, but not all, of the Orange Book patents while holding the others in reserve for future litigation; (2) by settling on advantageous terms with the first filer and refusing to litigate with subsequent applicants; or—as in this case—(3) by settling with the first filer and suing subsequent applicants on some, but not all the Orange Book patents that the first filer certified under Paragraph IV. Each of these actions injures the subsequent ANDA applicants,

frustrates the Hatch-Waxman's goal of early resolution of patent disputes, and undermines Congress's intent to foster early generic market entry. *See* 149 Cong. Rec. S15885 (Nov. 25, 2003).

"[T]o prevent patentees from 'gaming' the Hatch-Waxman Act," Congress enacted the "civil action to obtain patent certainty," which allows ANDA applicants to bring a declaratory judgment action challenging any Orange Book patents the NDA holder does not file suit on within 45 days of receiving a Paragraph IV Certification. *See* 21 U.S.C. § 355(j)(5)(C). In adding this provision, Congress specifically contemplated the "bottleneck" situation which occurs when a first filer's exclusivity is parked:

> [W]hen generic applicants are blocked by a first generic applicant's 180-day exclusivity, [and] the brand drug company [attempts] . . . to delay a final court decision that could trigger [the exclusivity] . . . generic applicants must be able to seek a resolution of disputes involving all patents listed in the FDA Orange Book . . . because the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes.

149 Cong. Rec. S15885 (Nov. 25, 2003). Congress extended federal jurisdiction over civil actions to obtain patent certainty "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5). Congress explained the need to extend federal jurisdiction over civil actions to obtain patent certainty as follows:

> [W]hen generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the "failure to market" provision and force the first generic to market.

149 Cong. Rec. S15885 (Nov. 25, 2003).

The "civil action to obtain patent certainty" "specifically permits an ANDA applicant to file a declaratory judgment action" to challenge the patents listed in the Orange Book, and "extend[s] federal court jurisdiction over these ANDA declaratory judgment actions." *Teva*

Pharms. USA, Inc. v. Novartis Pharms. Corp., 482 F.3d 1330, 1342-43 (Fed. Cir. 2007). As the Federal Circuit has explained, a "NDA holder's use of an Orange Book-listed patent to exclude a generic drug maker from the market creates 'the exact type of uncertainty of legal rights that the ANDA declaratory judgment action [i.e., the CAPC, 21 U.S.C. § 355(j)(5)(C)] was enacted to prevent." *Caraco*, 527 F.3d at 1292 (quoting *Novartis*, 482 F.3d at 1345). A "declaratory action is the ideal method to police [the patentee's] strategic manipulation of the Hatch-Waxman exclusivity provisions." *Teva Pharms. USA, Inc. v. Pfizer Inc.*, 405 F.3d 990, 995 (Fed. Cir. 2005).

B. Statement of Facts

Sepracor holds an approved NDA for various strengths of levalbuterol hydrochloride inhalation solutions used for the treatment of bronchial disorders and sold under the trade name Xopenex®. Sepracor identified six patents to the FDA for listing in the Orange Book, namely U.S. Patent Nos. 5,362,755, 5,547,994, 5,760,090, 5,844,002, 6,083,993 ("the method-of-use patents"), and U.S. Patent No. 6,451,289 ("the '289 patent"). The method-of-use patents are directed to methods of therapeutically using XOPENEX® to treat asthma while the '289 patent claims, *inter alia*, a levalbuterol hydrochloride solution product free of chelating agents.

In 2005, Dey filed ANDA No. 77-800 with the FDA seeking approval to market its 3 mL dosage strengths generic levalbuterol hydrochloride inhalation solutions (1.25 mg/ 3 mL, 0.063 mg/3 mL and 0.31 mg/3 mL) ("3 mL levelabuterol"). As part of its ANDA, Dey filed a Paragraph IV Certification stating each of the six Orange Book patents were invalid or not infringed by Dey's ANDA product. As statutorily required, on January 9, 2006, Dey notified Sepracor it filed Paragraph IV Certifications for the six Orange Book patents. On February 22, 2006, within the 45-day period, Sepracor filed a patent infringement lawsuit against Dey asserting five of the six Orange Book patents. Sepracor did not sue Dey for infringement of the

'289 patent which claims, *inter alia*, a levalbuterol formulation free of chelating agents. Dey's ANDA product contains a chelating agent and therefore, cannot infringe the '289 patent.

Dey received tentative approval from the FDA for its ANDA product on February 7, 2008. This Court held a Markman Hearing on July 18, 2008, and has notified the parties to be prepared to go to trial 90 days after the Court issues its Markman decision. However, even if the five patents upon which Dey was sued are held by this Court to be invalid or not infringed, the applicable regulatory scheme prohibits the FDA from granting final approval for Dey's 3 mL levalbuterol. This is because another generic drug manufacturer, Breath Ltd. ("Breath"), was the first to file an ANDA for 3 mL levalbuterol with Paragraph IV Certifications entitling it to 180 days of market exclusivity. As explained above, the statute prohibits the FDA from granting final approval to any ANDAs for 3 mL levalbuterol until Breath's 180-day exclusivity is triggered.

Sepracor sued Breath for infringement of all six of its Orange Book patents. Breath's 180-day exclusivity will begin either on the day it begins marketing its generic drug, or on the date a court enters consent decrees that all six Orange Book patents Breath certified under Paragraph IV are invalid or not infringed.

The Breath case was scheduled to go to trial in July 2008. On May 1, 2008, Sepracor and Breath announced that they had settled their litigation without the entry of a consent decree that each of the six patents are either invalid or not infringed. As part of the settlement, Breath agreed not to go to market before August 20, 2012[1], unless other generics entered the market earlier. Additionally, Breath agreed to purchase its raw material from Sepracor, and to pay

[1] Dey requested a copy of the settlement agreement from Sepracor. Sepracor responded by sending a redacted copy that was part of a public SEC filing. Dey has requested an unredacted copy. The settlement and license agreement prohibits Breath from marketing its product before August 2012 unless another generic goes to market earlier. There is no requirement, however, that Breath market its product (and trigger its exclusivity) at all.

Sepracor a royalty on any product it sells. *See* Exs. 1 and 2.[2] As explained above, until a judgment or consent decree of noninfringement or invalidity is entered with respect to all six of the Orange Book patents—including the '289 patent, which Sepracor did not assert against Dey—Dey cannot obtain final approval to market its ANDA product. Should Breath choose not to market its product, Dey's product will be kept off the market until the '289 patent expires in 2021, thirteen years after the date it received tentative FDA approval, even though its ANDA product cannot infringe the '289 patent. Faced with the potential for market delay due to Sepracor's settlement with Breath, and with knowledge that it did not infringe the '289 patent because Dey's product contains a chelating agent, Dey filed a complaint seeking a declaratory judgment that the product which is the subject of its ANDA does not infringe the '289 patent.[3]

On August 12, 2008, in a transparent attempt to delay generic competition, Sepracor unilaterally granted Dey a covenant not to sue on the '289 patent. The covenant states that it has no bearing upon: (a) whether the 3 mL levalbuterol that is the subject of Dey's ANDA infringes any claim of the '289 patent; or (b) whether the '289 patent is unenforceable or invalid. *See* Ex. 4. Sepracor's carefully worded covenant not to sue does not trigger Breath's exclusivity period because, as discussed above, the applicable regulatory scheme requires a consent decree of invalidity or noninfringement entered by the Court to trigger Breath's exclusivity. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II). That is, Breath's exclusivity has been "parked"—the precise manipulation of the statute the MMA was supposed to eliminate.

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[2] "Ex. __" refers to exhibits attached to the accompanying September 2, 2008 Declaration of Sam V. Desai.

[3] Sepracor makes much of the fact that Dey did not file a declaratory judgment action earlier. However, if Dey had filed its declaratory judgment action prior to the Breath settlement, Sepracor would, no doubt, have filed a motion to dismiss for lack of subject matter jurisdiction, arguing that because the '289 patent was being litigated in the *Breath* case and that any delay in Dey receiving final approval was due to Breath's statutorily mandated 180-day exclusivity. Indeed, Sepracor made this precise argument to this Court on March 7, 2008. *See* Ex. 3, 3/7/08 Tr. at 20: 14-21.

III. ARGUMENT

A. Dey's Declaratory Judgment Action Presents an Article III Controversy Because It Satisfies the "All-The-Circumstances" Test

The Article III controversy and attendant legal injury in this case are straightforward. Sepracor's actions effectively prevent the FDA from approving Dey's ANDA, thereby excluding Dey's 3 mL levalbuterol from the market. By listing six Orange Book patents, suing Dey on only five of the six Orange Book patents, and not filing a consent decree of non-infringement or invalidity on the sixth patent—the '289 patent, Sepracor has created a legal barrier that delays Dey's product from entering the market. Dey can clear this barrier and trigger Breath's exclusivity only by obtaining a judgment or a consent decree that its 3 mL levalbuterol does not infringe the '289 patent.

Prior to the Supreme Court's decision in *MedImmune,* the Federal Circuit required declaratory judgment plaintiffs to demonstrate "an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit." *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1330 (Fed. Cir. 2005). In *MedImmune* the U.S. Supreme Court struck down the so-called "reasonable–apprehension-of-suit test" when it found the test inconsistent with its precedent. *Caraco*, 527 F.3d at 1288 (citing *MedImmune*, 127 S. Ct. at 774 n.11 (2007)).

After *MedImmune*, the Federal Circuit adopted the "all the circumstances test," which the Supreme Court held in *MedImmune* was in keeping with the general principles of Article III. *Id.* To establish a justiciable declaratory judgment controversy under this test, a plaintiff need only show that "the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* at 1290

The material facts of this case are essentially identical to *Caraco*, in which the Federal Circuit held that a patentee's covenant not to sue did not eliminate the Article III controversy between parties in a Hatch-Waxman litigation. In *Caraco*, Forest held a NDA for the drug Lexapro®, and listed two patents U.S. Patent Nos. Re: 34,712 ("the '712 patent") and 6,916,941 ("the '941 patent") in the Orange Book. *Caraco*, 527 F.3d at 1286. Ivax was first to file a Paragraph IV Certification on Forest's two Orange Book patents, and was sued by Forest on only the '712 patent. *Id.* Ivax lost its invalidity and non-infringement challenge on the '712 patent. *Id.* As a result, Ivax's drug could not enter the market until 2012, the expiration date of the '712 patent. *Id.* at 1287.

Caraco, the second ANDA filer, also filed a Paragraph IV Certification on Forest's two Orange Book patents. *Id.* at 1288. Again, Forest sued only on the '712 patent. While the litigation on the '712 patent was ongoing, Caraco brought an action seeking a declaratory judgment of non-infringement with respect to the second patent—the '941 patent. *Id.* Forest subsequently provided Caraco with a covenant not to sue on the '941 patent and filed a motion to dismiss Caraco's declaratory judgment action. *Id.* at 1288-89.

The district court ruled that there was no Article III controversy because the covenant not-to-sue eliminated any case or controversy. *Id.* at 1290. The Federal Circuit reversed. In rendering its decision, the Federal Circuit applied the 3-pronged "all-the-circumstances" test mandated by the Supreme Court. The Federal Circuit held Caraco's declaratory judgment action presented an Article III controversy because: (1) Caraco had standing to bring a declaratory judgment action; (2) the issues were ripe for judicial review; and (3) the case was not rendered moot by Forest's covenant not to sue on the '941 patent. *Id.* at 1291-97. Dey's declaratory judgment action, likewise, meets the three prongs of the "all-the-circumstances" test.

1. Dey Has Standing to Bring Its Declaratoy Judgment Action

Dey has standing to bring its declaratory judgment action, if it: (i) alleges an injury in fact; (ii) shows causation between Dey's injury and Sepracor's conduct; and (iii) demonstrates a likelihood that the requested relief will redress the alleged injury. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102-03 (1998). Each factor is present in this case.

a. Dey Can Show Injury-In-Fact

In this case, Breath's exclusivity has been "parked." Sepracor settled its case against Breath without the entry of a consent order stating the Orange Book patents were invalid or not infringed, and with an agreement that Breath will not enter the market, and will therefore not trigger its exclusivity, until August 2012 at the earliest. As discussed above, to trigger Breath's exclusivity Dey must obtain a judgment or consent decree on all six Orange Book patents. This includes the '289 patent, which is the subject of this action and which Dey cannot infringe. Although Sepracor (like Forest in the Caraco case) covenanted not to sue Dey on the '289 patent, as discussed above the statute requires entry of a consent decree of non-infringement or invalidity to trigger Breath's exclusivity.

Thus, if the Court grants Sepracor's motion to dismiss, and Dey prevails in the patent action Sepracor brought against it as to the other five patents, Breath's exclusivity will not be triggered and Dey's product will be kept off the market. Indeed, Dey's product can be kept off the market until 2021, when the '289 patent expires, even though its ANDA product cannot possibly infringe the patent. It is settled Federal Circuit law that a market delay such as would occur in this case is a "direct legal injury . . . which requires judicial relief." *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F. 3d 1330, 1345 (Fed. Cir. 2007).

In *Caraco*, the Federal Circuit held that delayed market entry due to actions taken by the patentee which delay FDA approval is an injury sufficient to create an Article III controversy:

> Ordinarily, a potential competitor in other fields is legally free to market its product in the face of an adversely-held patent. In contrast, under the Hatch-Waxman Act an ANDA filer . . . is not legally free to enter the market [without FDA approval] . . . Thus, by preventing the FDA from approving the ANDAs of generic drug manufacturers, pharmaceutical patentees like Forest can potentially exclude non-infringing generic drugs from the market. If Caraco is correct, that its generic drug does not infringe Forest's [unasserted Orange Book patent], then it has a right to enter the generic drug market, and its exclusion from the generic drug market by Forest's actions is a sufficient Article III injury-in-fact.

Caraco, 527 F.3d at 1291-92 (citing *Novartis*, 482 F.3d at 1345). Because Dey will be prevented from entering the market absent a consent decree that the '289 patent is not infringed by Dey's product, the injury to Dey is "concrete and actual or imminent, not conjectural or hypothetical." *Id.* at 1291.

If this action is dismissed, Dey will be:

> 'restrain[ed from] the free exploitation of non-infringing goods,' *Red Wing Shoe Co., Inc. v. Hockerson-Halberstadt, Inc.*, 148 F.3d 1355, 1360 (Fed. Cir. 1998). This is exactly the type of injury-in-fact that is sufficient to establish Article III standing under our caselaw.

Caraco, 527 F.3d at 1292. Accordingly, injury-in-fact exists in this case.

b. Dey's Injury Is Traceable to Sepracor's Conduct

An Article III controversy requires not only an injury-in-fact, but also "causation—a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant." *Steel Co.*, 523 U.S. at 103. Here, Dey's injury, the inability to enter the market for generic levalbuterol hydrochloride is directly traceable to Sepracor's conduct because of: (1) Sepracor's listing of the method-of-use and '289 patents; (2) Sepracor's infringement suit challenging Dey's ANDA; and (3) Sepracor's failure to either sue Dey on the '289 patent or to enter a consent decree of no infringement. In attempting to argue that Dey's injury is traceable to a party other than Sepracor, Sepracor states that it arguably "had the least to do with the fact

that Dey will have to wait for Breath to enjoy the 180-day exclusivity that the Hatch-Waxman Act framers intended that it have." (Sepracor Br. at 14). But the Federal Circuit rejected this argument in *Caraco* explaining that if a patentee had not listed its patents in the FDA's Orange Book as valid patents covering the drug described in its NDA for its drug, then 21 U.S.C. § 355 (j)(5)(B)(iv) would not independently delay the generic's ANDA from being approved by the FDA. *Caraco*, 527 F.3d at 1292.

Even if as Sepracor argues it was required by statute to list the '289 patent in the Orange Book, Sepracor chose to use the '289 patent to block entry of Dey's product by structuring a settlement in a way which would prevent Breath's 180-day exclusivity from being triggered (i.e., using a settlement agreement to "park" exclusivity—precisely what the MMA amendments were enacted to avoid). Moreover, despite the fact that Sepracor did not sue Dey on the '289 patent because Dey's product cannot infringe it, Sepracor has failed to agree to the entry of the statutorily required consent decree that Dey's ANDA product does not infringe the '289 patent. Instead, Sepracor filed a covenant not to sue, knowing at the time that a covenant not-to-sue is insufficient under the triggering statute. "It is well established that the creation of such barriers to compete satisfies the causation requirement of Article III standing." *Id.* at 1293 (citations omitted).

c. A Favorable Judgment Will Redress Dey's Injury

Not only has Dey suffered an injury-in-fact fairly traceable to Sepracor's conduct, but a favorable court decision would redress that injury. The redressibility requirement of Article III is satisfied when it is "'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'" *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). Here, a favorable court decision would eliminate a delay in Dey's entry into the 3 mL

levalbuterol hydrochloride market caused by the lack of a judgment or consent decree that the '289 patent is invalid or not infringed.

Sepracor argues that Dey's injury-in-fact is hypothetical because Dey must still prevail in its lawsuit with respect to the method-of-use patents. (Sepracor Br. at 12). Sepracor's argument is misplaced. Sepracor fails to recognize that the injury, upon which Dey's suit is premised is the injury caused by a delay in triggering Breath's exclusivity period because there is no finding of non-infringement of the '289 patent in the settlement agreement entered by the Court in that case. A judgment of noninfringement in this action will eliminate Dey's exclusion from the market due to the '289 patent.

Sepracor argues that Dey's market entry is "completely speculative" because there has been no decision on the method-of-use patents. Sepracor's argument fails for the same reason Forest's failed in the *Caraco* case. The Federal Circuit found Caraco's injury would be redressed despite the fact that Forest's suit against Caraco on the '712 patent was not resolved.

> If Caraco obtains a favorable judgment that the drug described in its ANDA does not infringe Forest's '941 patent then it will only need a judgment of invalidity or non-infringement on Forest's '712 patent in order to activate Ivax's exclusivity period and obtain FDA approval as swiftly as possible. Thus a favorable judgment in this action would eliminate the potential for the '941 patent to exclude Caraco from the drug market.

Caraco, 527 F.3d at 1293.

Moreover, Sepracor's argument that "it is likely–not just possible–that Breath's 180-day exclusivity will be triggered by Breath's own marketing before that 180-day period would ever be a barrier to Dey's market entry" is itself completely speculative. Based upon the news report and the redacted settlement and licensing agreement filed with the Securities and Exchange Commission, there is nothing that would require Breath to go to market in 2012. What the Court must consider is that as a result of Sepracor's settlement with Breath and its failure to enter a

consent decree of non-infringement, the '289 patent could prevent Dey from going to market until 2021, when the patent expires, irregardless of when the method-of-use patents expire and despite the fact that the Dey product cannot infringe the '289 patent. Indeed, Sepracor itself recognized this in March when it argued to this Court "[t]he fact is that Brett [sic] is the first filer and Brett[sic]is holding everyone else up. There is no question about that." *See* Ex. 3, 3/7/08 Tr. at 20: 14-16. As shown above, Dey meets the three-part test for standing—Dey suffers injury-in-fact that is traceable to Sepracor and the injury can be redressed by a favorable judgment.

2. Dey's Action is Ripe for Judicial Review

An action is "ripe" for judicial review where: (1) further factual development would not significantly advance a court's ability to deal with the legal issues presented; and (2) withholding court consideration of an action causes hardship to the plaintiff where the complained-of conduct has an "immediate and substantial impact on the plaintiff." *Caraco*, at 1294-95. Here, both prongs of the ripeness inquiry are met. First, additional facts would not advance this Court's ability to decide Dey's action for a declaratory judgment of non-infringement. Dey has a complete generic drug product that has been submitted to the FDA, it has received tentative approval and no additional facts are required to determine whether Dey's drug product infringes the claims of Sepracor's '289 patent. Second, if Dey's drug does not infringe Sepracor's '289 patent, then withholding this Court's consideration of Dey's declaratory judgment action has the "immediate and substantial impact" of forestalling Dey's ability to trigger Breath's exclusivity period through the court-judgment trigger.

Sepracor does not argue that Dey's action is not ripe for review. And, under *Caraco* it cannot. In *Caraco*, the Federal Circuit held that Caraco's action was ripe for judicial review because: (1) Caraco filed a complete ANDA and no additional facts were needed to determine whether Caraco's product infringed; and (2) withholding consideration of Caraco's declaratory

judgment action had the immediate and substantial impact of forestalling Caraco's ability to activate Ivax's exclusivity period through the court judgment trigger. *See Caraco*, 527 F.3d at 1295. The same facts are present in this case. Accordingly, Dey's action for a declaratory judgment is ripe for judicial review.

3. Sepracor's Covenant Not to Sue Does Not Affect the FDA's Authority to Approve Dey's ANDA, Therefore, Dey's Action Is Not Rendered Moot

The Federal Circuit stated in *Caraco* that "[t]he mootness doctrine requires that the requisite personal stake that is required for a party to have standing at the outset of an action must continue to exist throughout all stages of the action." *Id.* at 1296. In *Caraco*, the Federal Circuit addressed whether a unilateral covenant not to sue on the patent that was the subject of the declaratory judgment action rendered the entire case moot. *Id.* The Federal Circuit explained that in the Hatch-Waxman context:

> [E]ven after a covenant not to sue has been granted, the dispute as to infringement or invalidity of the relevant Orange-Book-listed patents constitutes a "substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

Id. (citations omitted). This is because a covenant is legally insufficient to trigger the 180-day exclusivity. FDA cannot grant final approval to Dey's 3 mL levalbuterol in the absence of a consent decree of invalidity or non-infringement on all patents Breath filed a Paragraph IV Certification.

Without a judgment of non-infringement or invalidity of the '289 patent, even if Dey prevailed against Sepracor in the separate action on the method-of-use patents, Dey could not trigger Breath's exclusivity period and go to market. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II). Thus, terminating this action without a judgment with respect to infringement or invalidity will delay final FDA approval of Dey's ANDA and thereby exclude Dey from the market, even though

Dey's 3 mL levalbuterol cannot infringe the '289 patent. Sepracor states that its covenant not to sue Dey on the '289 patent "narrows the issues for the current motion to dismiss." (Sepracor Br. at 6). Sepracor is wrong. Under the Hatch-Waxman statutory scheme, Sepracor's covenant not to sue does not "narrow" or eliminate the controversy between Sepracor and Dey. As the Federal Circuit explained under materially identical facts in *Caraco*, a covenant not to sue is statutorily insufficient to activate the court judgment trigger of the first filer's exclusivity:

> Here, Forest's covenant not to sue Caraco does not allow Caraco to enter the generic drug market. Only by obtaining a judgment of non-infringement on both the '712 and '941 patents can Caraco trigger Ivax's 180-day exclusivity period, which currently prevents the FDA from approving Caraco's ANDA. Without a judgment of noninfringement on the '941 patent, even if Caraco prevailed against Forest in the separate infringement action on the '712 patent, Caraco would not be able to activate Ivax's exclusivity period via the court-judgment trigger of 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). Moreover, until Ivax's exclusivity period expires, the FDA cannot approve Caraco's ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (2000). Thus, terminating this action without a judgment with respect to infringement on the '941 patent could delay FDA approval of Caraco's ANDA and thereby exclude Caraco from the drug market, even if its generic drug does not infringe the '941 patent. In these circumstances, Forest's covenant not to sue Caraco does not eliminate the controversy between the parties.

Id. at 1297.

* * *

Sepracor's motion to dismiss should be denied because this Court has subject matter jurisdiction over Dey's declaratory judgment action. The action meets all three prongs of the "all-the-circumstances" test set out by the Federal Circuit to determine whether an action presents an Article III controversy. As detailed above, Dey has standing to bring the action, the issue is ripe for judicial review, and it is not rendered moot at any stage in the litigation. Accordingly, Sepracor's motion should be denied.

B. Sepracor Has Failed to Distinguish *Caraco*

Sepracor attempts to distinguish *Caraco* by arguing that Dey's injury is "completely hypothetical at this point in time," and that Dey cannot link its injury to Sepracor's conduct. (Sepracor Br. at 14). The very same arguments were advanced by the patentee in *Caraco* and rejected by the Federal Circuit. Specifically, the Federal Circuit held that the "exclusion from the generic drug market by [the patentee's] actions is a sufficient Article III injury in fact." *Caraco*, 527 F.3d at 1292. Similarly, with respect to causation or traceability, the *Caraco* court found that that the act of listing patents in the Orange Book and not suing Caraco (or stipulating to a judgment of non-infringement) was a "but for" cause of delaying Caraco's ANDA approval and "is sufficient to satisfy the traceability requirement of Article III standing." *Id.*

This declaratory judgment action is necessary to eliminate Sepracor's ability to block Dey's entry into the market based upon the '289 patent. Sepracor argues that "Sepracor had the least to do with the fact that Dey will have to wait for Breath to enjoy the 180-day exclusivity." Being second to file[4] is not a "but for" cause of Dey being blocked from entering the market. The injury to Dey is not that it did not get 180 days of exclusivity, but rather—due to Sepracor's actions relating to the '289 patent—Dey is prevented from triggering Breath's exclusivity delaying its entry into the market. (Sepracor Br. at 14). The purpose of the MMA amendments was in part to establish triggering mechanisms so that the exclusivity of a first filer could not be "parked" and block subsequent filers from entering the market.

Moreover, the fact that the Hatch-Waxman Act and Breath's exclusivity period are also relevant to Dey's injury does not render that injury any less traceable to Sepracor. Article III jurisdiction exists where more than one factor arguably caused the plaintiff's injury. *See e.g.*, *Bennett v. Spear*, 520 U.S. 154, 168-69 (1997) (an injury is "fairly traceable" to the defendant

[4] That Dey was second to file does not distinguish this case from Caraco. Caraco was also second to file.

even if the defendant's actions are not "the very last step in the chain of causation"). In short, there is no doubt that Dey's inability to market its product is "fairly traceable" to Sepracor's conduct of listing its patents in the Orange Book and failing to either sue Dey on all of the listed patents or enter a consent decree of non-infringement on those patents.

Sepracor's argument that Dey's injury is "completely hypothetical at this time" is similarly without merit. Like Dey, Caraco was also involved in litigating another Orange Book patent at the time it filed its declaratory judgment action. Sepracor does not dispute that absent a favorable ruling on the '289 patent, Dey cannot enter the market until 180 days after Breath enters the market, and under the terms of its settlement agreement, the earliest Breath can enter the market is August 20, 2012 (eight years prior to the expiration of the '289 patent). If Dey obtains final judgment of invalidity or noninfringement on the method of use patents prior to Breath going to market (and there is no guarantee that Breath will go to market on August 20, 2012), Dey will be blocked from entry by the failure to resolve the '289 patent controversy. Thus, terminating this action without a judgment with respect to non-infringement of the '289 patent would delay FDA approval of Dey's ANDA and thereby exclude Dey from the drug market, even though its levalbuterol hydrochloride does not infringe the '289 patent. These are the same circumstances that existed in Caraco. Dey's injury is no more hypothetical than Caraco's was at the time the Federal Circuit determined an Article III controversy existed in that case.

C. This Court Should Not Use Its Discretion to Dismiss this Case

Although the "all-the-circumstances" test is "dispositive" in establishing an Article III controversy exists, Sepracor asks this Court to use its discretion to dismiss this case. As discussed above, Dey's declaratory judgment is consistent with both the language and the intent of the Hatch-Waxman Act as amended by the MMA. Title 21 U.S.C. § 355(j)(5)(C) specifically

permits an ANDA applicant to file a declaratory judgment action under 28 U.S.C. § 2201 against the patent owner or the brand-name drug company "for a declaratory judgment that the patent [listed in the Orange Book] is invalid or will not be infringed by the drug covered by the ANDA if the patentee has not brought an infringement action within 45 days." *Novartis*, 482 F.3d at 1342. The purpose of this provision was to prevent NDA holders from blocking entry by not resolving the infringement or invalidity issues relating to each of the Orange Book patents.

Sepracor fails to address the fact that in the ANDA context, Congress explicitly extended federal court declaratory judgment jurisdiction under 28 U.S.C. § 2201 to ANDA Paragraph IV disputes "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5). Dey's lawsuit here seeks to further the "central purpose of the Hatch-Waxman Act," which is "to enable competitors to bring cheaper, generic . . . drugs to market as quickly as possible." *Novartis*, 482 F.3d at 1344 (citing 149 Cong. Rec. S15885 (Nov. 25, 2003)). Here, Sepracor's actions frustrate this very purpose and create a basis for finding a justiciable controversy.

Sepracor argues that judicial resources would be better spent by litigating the '289 patent after the court decides the pending action involving the method-of-use patents. (Sepracor Br. at 17). But Sepracor misses the point. A favorable judgment in this action would eliminate the potential for the '289 patent to exclude Dey from the drug market. The Federal Circuit not only recognized this very injury, but also found that it could be redressed only by maintaining jurisdiction over the declaratory judgment brought by the subsequent ANDA filer. *See Caraco*, 527 F.3d at 1293.

Sepracor stresses its motion should be granted because it will promote judicial economy. Sepracor is wrong. If Sepracor had desired to eliminate this action from the court's docket for purposes of judicial economy, it would have filed a consent decree that Dey's 3 mL levalbuterol does not infringe the '289 patent. Sepracor's decision to provide a covenant not to sue, rather

than the statutorily required consent decree reveals its true purpose—delay. If the Court dismisses this action, Dey will have to bring this same action after the method of use patents are resolved, causing additional delay to Dey's entry into the market and the public's access to lower-cost 3 mL levalbuterol.

Finally, Sepracor argues that in determining whether to dismiss this case, the Court should take Dey's first filer status on the levalbuterol concentrate ANDA into consideration. As an initial matter, it is not clear why Dey's filing status with respect to the concentrate product is relevant to this case. Since Dey was the first filer on the concentrate, and Sepracor sued Dey only on the method of use patents, the '289 patent is irrelevant to this declaratory judgment action. If Sepracor means to imply that Dey's sales of the concentrate would somehow reduce or negate Dey's injury in this case, Sepracor is turning the argument it made to this Court in its motion to consolidate the Dey case with the Barr case on its head. Dey argued consolidation would prejudice it because consolidation would slow down the court's consideration of the method of use patents and, thereby, have an adverse effect on Dey's market entry for the concentrate. Sepracor responded that Dey would not be prejudiced because the sales of the concentrate are "relatively insignificant compared to the other dosage strengths." (Ex. 5 Sepracor's Reply in Supp. of Consolidation, at 2.) Now Sepracor is taking the opposite position to argue Dey will not be injured by a delay in the resolution of this case because it will be able to enter the concentrate market without a judgment on the '289 patent. The Court should not entertain Sepracor's arguments regarding Dey's concentrate solution, particularly when the position Sepracor advances changes depending upon the issue it is arguing.

In sum, there is no good reason why this Court should use its discretion to delay resolution of the Article III controversy raised in Dey's motion for declaratory judgment. Accordingly, Sepracor's motion should be denied.

IV. CONCLUSION

For the reasons set forth above, Dey respectfully requests the Court deny Sepracor's motion to dismiss and conclude that it has subject matter jurisdiction over Dey's declaratory judgment action against Sepracor.

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